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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/610,152	07/05/2000	Napoleone Ferrara	9491-043-27 DIV	4661

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PIPER MARBURY RUDNICK & WOLFE LLP
STEVEN B KELBER
1200 NINETEENTH STREET, NW
WASHINGTON, DC 20036-2412

EXAMINER	
WEBER, JON P	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 03/05/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/610,152	FERRARA ET AL.	
	Examiner	Art Unit	
	Jon P Weber, Ph.D.	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09 December 2002 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 16-27 have been renumbered as 17-28. Previous claim 16 presented with the response after Final of 21 June 2002 was not entered. Only claims 17-28 are currently pending and considered on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 17-18 and 21-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Chamow et al. US 5,849,689).

Chamow et al. US 5,849,689) disclose a composition comprising: **0**, 0.1 or 10 μg/ml heparin and about 0 and 40 μg/ml of HGF (Fig 2) diluted in solution containing 0.1% BSA, PBS (aka=phosphate buffered saline, a standard physiologically compatible solution), and 0.05% Tween-20 (aka=polyoxyethylene sorbitan monoleate); see example 2 at column 13. Absence of heparin was the standard. N.B. Tween-21 is the monolaurate ester.

Claims 17-18 and 21-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Wilson (US 5,703,047).

Wilson (US 5,703,047) discloses preparing compositions of HGF in a pharmaceutically acceptable sterile aqueous solution comprising: preservative, buffers, antioxidants, tonicity agents, stabilizers, wetting and clarifiers *inter alia* (column 5, lines 40-67). The preservatives include thimerosal (column 6, lines 1-30; the buffers include phosphates buffered to a pH between 7 and 7.5 (column 6, lines 3-8); tonicity agents include dextrose and sodium chloride to be isotonic (column 6, lines 9-12); wetting and clarifiers include polysorbate 80 (aka=

polyoxyethylene sorbate monoleate) and polysorbate 20 (aka= polyoxyethylene sorbate monolaurate) (column 6, lines 14-16). In example 4, the specific combination of 50-500 ng/ml HGF in physiological phosphate buffered saline (pH 7.0) is described. Similarly, in the experiments described at columns 21-22, HGF in phosphate buffered saline and 0.2% gelatin is described.

Claims 17-18 and 21-27are rejected under 35 U.S.C. 102(b) as being anticipated by Nakamura et al. (US 5,342,831).

Nakamura et al. (US 5,342,831) disclose a solution (after dialysis against PBS) comprising HGF, 0.25% BSA and PBS (column 6, lines 28-31).

Claims 17-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Roos et al. (US 5,703,048) or under 35 U.S.C. 102(b) as being anticipated by Jardieu (US 5,227,158).

Roos et al. (US 5,703,048) and Jardieu (US 5,227,158) disclose at column 29, lines 10-21 and column 7, lines 6-17 respectively that HGF compositions are formulated with a suitable carrier according to Remington's. For injectable solutions, a typical vehicle includes saline, dextrose, Ringer's, etc.

Claim Rejections - 35 USC § 103

Claims 17-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chamow et al. US 5,849,689), Wilson (US 5,703,047), Nakamura et al. (US 5,342,831), Roos et al. (US 5,703,048) and Jardieu (US 5,227,158).

The teachings of Chamow et al. US 5,849,689), Wilson (US 5,703,047), Nakamura et al. (US 5,342,831), Roos et al. (US 5,703,048) and Jardieu (US 5,227,158) have been discussed above. None of Chamow et al. US 5,849,689), Wilson (US 5,703,047), Nakamura et al. (US 5,342,831), Roos et al. (US 5,703,048) and Jardieu (US 5,227,158) individually teaches the specific combination of all of the four of the ingredients in claim 28 with HGF.

A person of ordinary skill in the art at the time the invention was made would have been motivated to combine the four ingredients because Wilson suggest combining all the ingredients together in an HGF composition. The relied upon references make it clear that each of these carriers and/or ingredients is well known in the art to be used with HGF to make pharmaceutical compositions. The selection of one ingredient or another appears to be an arbitrary matter of experimental design choice. That is the specific ingredients are selected for their known and expected properties and suitability for a particular application. This selection is within the skill of the ordinary artisan in medicinal chemistry and pharmacology.

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine BSA, thimerosal, polysorbate 80, and PBS with HGF to produce a pharmaceutical composition suitable for injection, for example.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 703-308-4015. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Jon P Weber, Ph.D.
Primary Examiner
Art Unit 1651

JPW
February 28, 2003